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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0573]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### **Proposed Project**

National HIV Surveillance System (NHSS) (OMB Control No. 0920-0573, Expires 02/29/2016) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

### **Background and Brief Description**

Data collected as part of the National HIV Surveillance System (NHSS) are the primary data used to monitor the impact of HIV infection in the United States. The NHSS provides critical

data that are used to describe the incidence and prevalence of HIV disease and the characteristics of infected persons. HIV surveillance data are used widely at the local, state and national levels for planning, evaluation and allocation of funding for HIV prevention and care programs.

The NHSS has been updated periodically as science, technology, and our understanding of HIV has evolved. CDC in collaboration with health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to stage 3 (AIDS), the end-stage disease caused by infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence and monitor patterns in HIV drug resistance and genetic diversity, as well as provide information on perinatal exposures in the United States.

The CDC surveillance case definition has been modified periodically to accurately monitor disease in adults, adolescents and children and reflect use of new testing technologies and changes in HIV treatment. Information is then updated in the case report forms and reporting software as needed.

In 2014, following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multi-test algorithms, including criteria for differentiating between HIV-1 and HIV-2 infection and for recognizing early HIV infection. Clinical (non-laboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition.

Modifications to data elements to accommodate the 2014 HIV case surveillance definition were approved in the last renewal of OMB Control No. 0920-0573. The revisions requested in this extension include modifications to currently collected data elements and forms to accommodate new testing technologies as well as clinical practice guidelines. Specifically, the HIV

Testing and Antiretroviral Use History section will be revised on the adult/adolescent and pediatric case report forms to include new laboratory tests, additional information on use of antiretroviral (ARV) medications for pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child-transmission among HIV infected women during pregnancy, and hepatitis B virus (HBV) treatment. Other changes include addition of dates to the address and patient ID fields to better track residence information and minor formatting changes to the form used for Perinatal HIV Exposure Reporting (PHER).

The revisions to this request also include the addition of burden hours for annual reporting by health departments for the Standards Evaluation Report (SER) and Annual Performance Report (APR). Findings from these reports are used to improve data quality and ensure the accuracy, timeliness, and completeness of the national HIV surveillance, as well as to monitor performance and progress in achieving both state and national HIV surveillance program objectives. Fifty-nine health departments funded for HIV surveillance will report a Standards Evaluation Report (SER) and APR annually.

CDC provides funding for 59 health departments to conduct adult and pediatric HIV case surveillance and report information to CDC. Health department staff compile information from laboratories, physicians, hospitals, clinics and other health

care providers to complete adult and adolescent and pediatric HIV confidential case reports. Updates to case reports are also entered into an electronic database by health departments, as additional information may be received from laboratories, vital statistics offices, or additional providers. Evaluations are also conducted by health departments on a subset of case reports (e.g., re-abstraction/validation activities and routine interstate de-duplication) in all jurisdictions.

Supplemental surveillance data are collected in a subset of areas to provide additional information necessary to estimate HIV incidence, to better describe the extent of HIV viral resistance and quantify HIV subtypes among persons infected with HIV and to monitor and evaluate perinatal HIV prevention efforts. Health departments funded for these supplemental data collections obtain this information from laboratories, health care providers, and medical records. CDC estimates that 25 health departments will be reporting data elements containing HIV Incidence Surveillance (HIS) data, 53 health departments will report additional data elements on HIV nucleotide sequences as part of Molecular HIV Surveillance (MHS), and 35 areas will be reporting data as part of 35 health departments will be reporting data collected as part of Perinatal HIV Exposure Reporting (PHER) annually. The total estimated annual burden hours are 50,504.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Health Departments	Adult HIV Case Report	59	1,061	20/60
Health Departments	Pediatric HIV Case Report	59	5	20/60
Health Departments	Case Report Evaluations	59	107	20/60
Health Departments	Case Report Updates	59	1,576	2/60
Health Departments	Laboratory Updates	59	6,303	1/60
Health Departments	HIV Incidence Surveillance (HIS)	25	2,288	10/60
Health Departments	Molecular HIV Surveillance (MHS)	53	829	5/60
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60
Health Departments	Annual Reporting: Standards Evaluation Report (SER)	59	1	8
Health Departments	Annual Reporting: Annual Performance Report (APR)	59	1	42

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